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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/234,847	01/22/99	LEVY	S PKZ-013CP

000959
LAHIVE & COCKFIELD
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HM12/0202

EXAMINER

RADIO, B

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 02/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/234,847

Applicant(s)
Levy et al.

Examiner
Barbara Badio

Group Art Unit
1616



☐ Responsive to communication(s) filed on _____.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 2, 4-7, and 29-51 is/are pending in the application.

Of the above, claim(s) 2, 4-6, and 30-51 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 7, and 29 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

2. Claims 1, 2, 4-7 and 29-51 are pending in the present application. Claims 2, 4-6, and 30-51 stand withdrawn from consideration as being drawn to a non-elected invention. Claims 1, 7 and 29 stand rejected as indicated below.

Election/Restriction

3. Applicant traverse the withdrawal of claims 2 and 4-6 from examination. The traversal is on the ground(s) that the definition of R_2 as defined by claim 2, does include the acylcarbonyloxy substituent of Applicant's elected invention. Applicant refers to page 9, line 34 through page 10, line 17 of the present specification and the recitation of "substituted alkyl" (i.e., alkoxy) for support. This is not found persuasive because according to the present specification, "substituted alkyls" refers to alkyl moieties having substituents replacing a hydrogen on one or more carbons of the hydrocarbon backbone (see page 10, lines 1-2). There is no indication that applicant intended the replacement of two hydrogen atoms with an oxo group. Thus, even if one

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substitutes an alkoxy with an alkylcarbonyl group, one gets an alkylcarbonylalkoxy group and not an acylcarbonyloxy group as defined by the elected species.

Claim Rejections - 35 USC § 102

4. **The rejection of claim 3 under 35 USC 102(b) over Bernardi et al. ('942) is made moot by the cancellation of the instant claim.**

5. **The rejection of claims 1 and 29 under 35 USC 102(b) over Bernardi et al. ('942) is maintained.**

Applicant argues that the definition of "5,9-substituted tetracycline compound" as defined by the present invention excludes substitution by hydroxy or hydrogen at the 5- and 9- ring positions. Applicant's argument was considered but not persuasive for the following reasons.

Although, the claims are read in light of the specification, they have to be interpreted as broadly as possible. The claims read broadly do not exclude substitution by hydroxy or hydrogen at the 5- and 9- ring positions and, thus, encompass compounds taught by Bernardi et al.

Applicant refers to page 3, lines 28-31 in support of the argument that the present invention does not intend substitution by hydroxy or hydrogen at the 5- and 9- ring positions. The passage referred to by applicant indicates that **an embodiment** of

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the present invention is compounds as indicated above. However, it does not imply that the claimed invention excludes tetracycline-type compounds having hydroxy or hydrogen attached to the 5- and 9- ring position. According to page 2, lines 1-8, the term "tetracycline" or tetracycline-type" compound include tetracycline and other tetracycline family members such as oxytetracycline, methacycline and doxycycline, all of which have a hydroxy group attached to the 5- ring position. Thus, based on the present specification, the claimed invention includes all tetracycline or tetracycline-type compounds, including those taught by the prior art.

For these reasons and those given in Paper No. 12, the rejection of claims 1 and 29 under 35 USC 102(b) over Bernardi et al. ('942) is maintained.

6. The rejection of claims 1 and 29 under 35 USC 102(b) over Bernardi et al. ('384) is maintained.

Applicant's argument and the examiner's response are as discussed above in #5.

Claim Rejections - 35 USC § 103

7. The rejection of claim 3 under 35 USC 103(a) over Bernardi et al. ('942) is made moot by the cancellation of the instant claim.

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8. The rejection of claims 1, 7 and 29 under 35 USC 103(a) over Bernardi et al. ('942) is maintained.

Applicant argues that the reference does not teach or suggest the presently claimed 5,9-substituted tetracycline compounds nor does it teach or suggest the replacement of a hydroxyl group at position 5 with other groups. Applicant also refers to the present specification for a showing of unexpectedly high antibiotic activity of the claimed compounds. Applicant's arguments were considered but not persuasive for the following reasons.

As indicated above in #5, the claimed invention encompasses the compounds taught by the prior art. In response to applicant's argument that the prior art does not teach or suggest replacement of a hydroxyl group at position 5 with other groups, the examiner directs applicant's attention to the definition of R_1 wherein it is defined by the prior art to include acyloxy. Thus, the prior art teaches the equivalence between a hydroxyl and an acyloxy at the 5-position and the replacement of hydroxy with an acyloxy group.

The examiner notes the data found on page 39 of the present specification. However, to show unobvious or unexpected results, applicant has to provide a side-by-side comparison of the closest prior art compound with the claimed compound(s). Said comparison is not provided by the present specification.

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry Contacts

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara Badio whose telephone number is (703) 308-4595. The examiner can normally be reached between 7:30 am and 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.


BARBARA P. BADIO, PH.D
PRIMARY EXAMINER

February 2, 2001



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1	LET.	1
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